Opioid-Free Anesthesia vs Opioid-Based Anesthesia in Laparoscopic Bariatric Surgery

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Statistical Analysis Plan – Summary

Opioid-free anesthesia versus opioid-based anesthesia in laparoscopic bariatric surgery
Randomized Controlled Trial

Study Design

Prospective, single-center, randomized, parallel-group clinical trial with 1:1 allocation comparing opioid-free anesthesia (OFA) with opioid-based anesthesia (OBA) in adult patients undergoing laparoscopic bariatric surgery.

Analysis Populations

Intention-to-Treat (ITT): All randomized participants will be analyzed according to their allocated group.
Per-Protocol (PP): Participants completing the study without major protocol deviations; used for supportive analyses.

Outcome Measures

- Primary Outcomes:

  Postoperative pain intensity assessed using the Numerical Rating Scale (NRS).
  Need for rescue analgesia during PACU stay and within the first 24 postoperative hours.

- Secondary Outcomes:

  Intraoperative nociception assessed using the Nociception Level Index (NOL).
  Incidence of postoperative nausea and vomiting (PONV).
  Need for PONV treatment.
  Patient satisfaction at hospital discharge.
  Postoperative complications and adverse events.

Statistical Methods

Continuous variables will be assessed for normality using the Shapiro–Wilk test and summarized as mean ± standard deviation or median with interquartile range, as appropriate. Between-group comparisons will be performed using the Student's t-test or Mann–Whitney U test. Categorical variables will be compared using Pearson's chi-square test or Fisher's exact test.

Multivariable generalized linear models will be used to adjust for potential confounders, including linear models for symmetric outcomes, Tweedie models with log link for asymmetric outcomes, and logistic regression for binary outcomes. Bonferroni correction will be applied where appropriate.

Missing Data

No imputation of missing data is planned. Analyses will be conducted using available data only, and the extent of missing data will be reported.

Safety Analysis

Adverse events and serious adverse events will be summarized descriptively by treatment group. No formal hypothesis testing is planned for safety outcomes.

Statistical Software

All statistical analyses will be performed using IBM SPSS Statistics version 28.0.